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| 09/518,642 | 03/03/2000 | Grady Lynn Holt | A7534 | 5821 |

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| EXAMINER |
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LEUNG, JENNIFER A

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| ART UNIT | PAPER NUMBER |
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1764

5

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/518,642 | HOLT, GRADY LYNN |
| Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- | Examiner | Art Unit |
| | Jennifer A. Leung | 1764 |

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) 8-10, 13, 14 and 16 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7, 11, 12, 15, 17 and 18 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03 March 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election without traverse of Group I (claims 1-7, 11-12 and 15) in Paper No. 5 is acknowledged. In addition, applicant's election with traverse of Group IA (claims 1-7 and 15) is acknowledged. The traversal is on the grounds that the Group IA and Group IB claims have the same function and provide the same result involving the same purpose, and furthermore, the addition of new claims 17-18 serve as linking claims which should permit examination of both Groups IA and IB together. Applicant's arguments are found persuasive, and therefore the restriction requirement between Groups IA and IB is withdrawn. Claims 1-7, 11-12, 15 and 17-18 will be examined together, as being drawn to the elected invention.
2. Claims 8-10, 13-14 and 16 (Group II) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

3. Claims 1, 11, 15, 17 and 18 are objected to because of the following informalities:
 - In claim 1, "said compressible section" (line 13) should be changed to -- said compression section -- for consistency in claim terminology. Likewise, claim 11 (line 8), claim 15 (lines 5, 11, 13), claim 17 (line 10), and claim 18 (lines 7, 8).
 - In claim 11, "said single use treatment vessel" (line 6) should be changed to -- said single use vessel -- for consistency in claim terminology. Likewise, claim 18 (line 6).
 - In claim 17, "position" (line 7) should be changed to -- positioned -- for proper grammatical form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-4, 6, 11, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 3-4, "said bottle" lacks proper positive antecedent basis, since it is interpreted that the applicants intended to recite, -- a frangible container --, and furthermore, "a frangible container" is merely recited in the intended use clause of claim 1, line 3.

With respect to claim 6, it is unclear as to where "said toxic chemical" is located, with respect to the elements of the apparatus. Likewise, in claim 11 (lines 10, 11).

With respect to claim 15, it is unclear as to the structural limitation applicants are attempting to recite by, "a single-use vessel holding a frangible container which contains said toxic chemical and a volume of treatment chemical," (lines 3-4), since the limitation reads that both toxic chemical and treatment chemical are contained within the frangible container, which is inconsistent with the specification.

With respect to claim 17, "*said frangible container* containing a toxic chemical" (lines 11-12) lacks proper positive antecedent basis, since "a frangible container" is merely recited in the intended use clause in line 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1, 3-4, 7, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519).

With respect to claims 1, 15 and 17, Ogle (FIG. 1-9; column 3, lines 1-65) discloses a compressible reactor/system comprising:

- A single-use vessel (i.e. outer container **10**) holding a frangible container (i.e. inner container **48** having a pierceable cap **52**, hence “frangible”) which may contain a toxic chemical and a volume of treatment chemical, depending on the intended use (column 1, lines 9-12; column 2, lines 14-16); said single-use vessel **10** having a compression section (i.e. accordianlike undulations **32**) and a treatment portion (i.e. the chamber, as defined by the walls of outer container **10**);
- A cover (i.e. end closure **14**) fastened to said single use vessel **10**; and
- An impact member (i.e. projection **34**) fixed to said cover **14**, wherein upon compression of said compressible section **32**, said impact member **34** breaks said frangible container **48, 52** (FIG. 3).

Ogle further discloses that for the means for compressing the compressible section, “the user simply compresses the package in an accordianlike fashion as shown in FIG. 3 to cause the

projection 34... to pierce the cap 52 on the inner container 48," (column 3, lines 37-41).

However, Ogle is silent as to whether the user's means for compressing may comprise specifically a jack and compression support frame, such that the jack is operative to extend between said cover and said compression support frame to compress the compressible section. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide a jack and compression support frame for the means for compressing in the apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the provision of mechanical or automated means to replace manual activity was held to have been obvious, *In re Venner* 120 USPQ 192 (CCPA 1958); *In re Rundell* 9 USPQ 220 (CCPA 1931); and the substitution of one known equivalent technique for another may be obvious even if the prior art does not expressly suggest the substitution, *Ex parte Novak* 16 USPQ 2d 2041 (BPAI 1989); *In re Mostovych* 144 USPQ 38 (CCPA 1964); *In re Leshin* 125 USPQ 416 (CCPA 1960); *Graver Tank and Manufacturing Co. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950). Furthermore, the use of jacks, coupled with a support frame, as a means for compressing is conventionally known in the art, as evidenced by Chaignay. In particular, Chaignay (Abstract, Figures) teaches a small hydraulic press comprising a jack (FIG. 2) attached to the upper surface 5 of a surrounding frame (comprising components 1, 2, 5), wherein in operation, an object (i.e. the compressible reactor of Ogle) which is placed upon the base of the frame is compressed by the jack via extension of the extendable shaft 20 (FIG. 1).

With respect to claim 3, Ogle further discloses said bottle 48, 52 (interpreted as meaning, "said frangible container") may be made of glass (column 3, lines 21-22), hence comprising a

"glass ampoule".

With respect to claim 4, although Ogle is silent as to whether the bottle **48, 52** (interpreted as meaning, "said frangible container") may contain a chemical weapon material, Ogle further discloses that said bottle **48, 52** and the single use vessel **10** are, "generally applicable to the storage and mixing... of *any* two reactive or nonreactive liquids or to the mixing of any liquid and solid," (column 1, lines 9-12) and that the device is, "particularly adapted for the handling of reactive, *toxic* and/or noxious chemicals," (column 2, lines 14-16). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select an appropriate chemical, such as a chemical weapon material, for the chemical in the apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof.

With respect to claim 7, Ogle further discloses, "closure **14**... has a lip **24** which engages and forms *a seal* on the upper end **26** of container **10**," (column 3, lines 5-7). A gasket may be defined as, "any of a wide variety of seals or packings used between matched machine parts or around pipe joints to prevent the escape of a gas or fluid," (The American Heritage® Dictionary of the English Language, Fourth Edition. Copyright © 2000 by Houghton Mifflin Company). Therefore, lip **24** of Ogle meets the claim of a "cover gasket".

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519), as applied to claim 1 above, and further in view of Loper (U.S. 3,087,638).

With respect to claim 2, Ogle (FIG. 1-8; column 3, lines 2-4) further discloses that the cover **14** may comprise a means for sampling the mixed chemicals, wherein the means comprises

a dispensing spout 16 having a fluid passage 18. However, Ogle is silent as to whether the means for sampling the mixed chemicals may comprise specifically a septum formed within said cover. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select a septum for the means for sampling in the apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the use of a septum as a means for sampling is conventionally known in the art, as evidenced by Loper. In particular, Loper teaches a septum (piston plug 30) for allowing a user to sample the contents of a container 15 using a piercing needle, wherein the needle is inserted through the penetrable material on the topside 29, 29a, 29b of the piston plug (Figures; column 1, lines 9-28; column 2, lines 70-73; column 3, lines 43-51). Furthermore, it has been held that substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

7. Claims 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519), as applied to claim 1 above, and further in view of Bolduc (U.S. 5,064,121).

With respect to claims 5 and 6, Ogle further discloses the frangible container may comprise indentations 50, "adapted to receive the inner edge of the bottom most of the accordionlike undulations 32 with a snap fit," such that, "the container 48 is restrained from longitudinal movement with respect to the outside container 10," (column 3, lines 25-31), essentially functioning as a holding means for the frangible container. However, Ogle is silent as to whether the holding means may comprise specifically a "cradle" for holding said frangible

container, wherein the cradle comprises penetrations. Bolduc (FIG. 1, 3, 6) teaches an apparatus for separately storing, mixing and dispensing two chemicals, substantially similar to the apparatus of Ogle, wherein the apparatus comprises a single-use vessel (external bottle or container 11) holding a frangible container (ampule or vial 49), wherein the mixing of the chemicals is initiated by the breaking of the frangible container 49 with an impact member (push rod 42). In particular, the frangible container 49 is held in place by a "cradle" (holder 53), which comprises a plurality of penetrations (vent holes 55). It would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to provide a cradle comprising penetrations for the holding means in the modified apparatus of Ogle, because the holder 53 provides a rigid support for the frangible container 49 while facilitating the mixing of materials via penetrations 55, as taught by Bolduc (column 3, lines 9-12, 48-50; column 7, lines 2-5, 58-61). Furthermore, substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

With respect to claim 18, Ogle (FIG. 1-8; column 3, lines 1-50) discloses a method of treating a toxic chemical (column 2, lines 14-17) using a single use vessel (outer container 10) having a compression section (accordionlike undulations 32), comprising the steps of:

- Placing a frangible container (comprising inner container 48, cap 52) in said single-use vessel 10 so that said frangible container 48, 52 is internally aligned with an impact member (projection 34);
- Inserting a treatment chemical (column 1, lines 9-12; column 4, lines 28-37) into said single use vessel 10; and

– Sealing said single-use treatment vessel 10 by providing an end closure 14 having a lip 24 which engages and forms a seal on the upper end 26 of container 10; such that the elements are, "... assembled in the fashion as shown in FIG. 1." (column 3, lines 34-37). However, Ogle is silent as to the particular order for conducting the steps above for obtaining the structure as shown in the Figure.

Bolduc (FIG. 1, 3, 6; column 8, lines 23-34) teaches an apparatus for mixing and dispensing two chemicals which are separately stored, substantially similar to the apparatus of Ogle, wherein the method for using the apparatus comprises the steps of:

- First, placing a frangible container (sealed ampule 49) into a single-use vessel 11 so that said frangible container 49 is internally aligned with an impact member (push rod 42);
- Second, inserting a treatment chemical (i.e. material 17) into said single use vessel; and
- Third, sealing said single-use treatment vessel 11 with cap 18.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to conduct the steps according to the order of Bolduc in the method of Ogle, since both processes are substantially identical or equivalent in terms of function, manner and result, and it has been held that where the processes are substantially identical or equivalent in terms of function, manner and result, transposition of process steps or the splitting of one step into two does not patentably distinguish the processes. *Ex part Rubin* 128 USPQ 159 (PO Bd PatApp 1959).

Ogle further discloses that after assembly of the apparatus, "[w]hen it is desired to admix the two ingredients, the user simply compresses the package in an accordionlike fashion as shown in FIG. 3 to cause the projection 34 with its sharp cutting edges 38 to pierce the cap 52 on the inner container 48." (column 3, lines 37-41). However, Ogle is silent as to whether the user's

means for compressing may comprise specifically operation of a jack, such that a force is exerted by said jack on the compressible section to compress the single-use vessel 10 and cause the impact member 34 to break the frangible container 48. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select a jack for the means for compressing in the method of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the provision of mechanical or automated means to replace manual activity was held to have been obvious, *In re Venner* 120 USPQ 192 (CCPA 1958); *In re Rundell* 9 USPQ 220 (CCPA 1931); and the substitution of one known equivalent technique for another may be obvious even if the prior art does not expressly suggest the substitution, *Ex parte Novak* 16 USPQ 2d 2041 (BPAI 1989); *In re Mostovych* 144 USPQ 38 (CCPA 1964); *In re Leshin* 125 USPQ 416 (CCPA 1960); *Graver Tank and Manufacturing Co. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950). In addition, such means for compressing is conventionally known in the art, as evidenced by Chaignay. In particular, Chaignay (Abstract, Figures) teaches a small hydraulic press comprising a jack (FIG. 2) attached to the upper surface 5 of a surrounding frame (comprising components 1, 2, 5), wherein in operation, an object (i.e. the compressible reactor of Ogle) which is placed upon the base of the frame is compressed by the jack via extension of the extendable shaft 20 (FIG. 1).

Lastly, although Ogle is silent as to shaking the single-use vessel to facilitate mixing between the treatment chemical and said toxic chemical, it would have been obvious for one of ordinary skill in the art at the time the invention to shake the contents of the single-use vessel in the modified method of Ogle, since it is conventionally known in the art that agitation by means

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of shaking facilitates mixing. To evidence conventionality, Bolduc further teaches "mixing of materials can be facilitated by shaking dispenser 10". (column 7, lines 54-58).

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519) and Bolduc (U.S. 5,064,121). The same comments with respect to Ogle, Chaignay, and Bolduc apply (see comments made in claim 18 above).

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519) and Bolduc (U.S. 5,064,121), as applied to claim 11 above, and further in view of Loper (U.S. 3,087,638).

With respect to claim 12, Ogle (FIG. 1-8; column 3, lines 2-4, 48-50) further discloses the step of dispensing or "sampling" the mixed chemicals from the apparatus via a sampling means comprising a dispensing spout 16 and a fluid passage 18. However, the collective teachings of Ogle, Chaignay, and Bolduc are silent as to a sampling means comprising a septum. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select a septum for the sampling means in the modified method of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the use of a septum as a sampling means is conventionally known in the art, as evidenced by Loper. The same comments with respect to Loper apply (see comments made in claim 2 above). Furthermore, it has been held that substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Cohen, Nighohossian et al. and Lechartier are presented to illustrate the state of the art.

* * *

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is 703-305-4951. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Calderola can be reached on 703-308-6824. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung
April 28, 2003 *JAL*

Hien Tran

**HIEN TRAN
PRIMARY EXAMINER**